

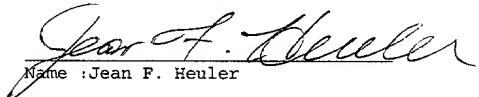
D-2973

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PATENT

In re application of:

Robert T. Lyon) Group Art Unit: N/A
Serial No. Pending) Examiner: N/A
Dated: Herewith)
For: USE OF ANTIMICROBIAL PEPTIDES)
AS PRESERVATIVES IN)
OPHTHALMIC PREPARATIONS,)
INCLUDING SOLUTIONS, EMULSIONS,)
AND SUSPENSIONS)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as "Express mail Post Office to Addressee" service under CFR 1.10 addressed to: Commissioner for Patents, Box New App Fee, Washington, DC 20231, on or before July 13, 2001.


Name :Jean F. Heuler

Date: July 13, 2001

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, DC 20231

Dear Sir:

Before the first action in this application, please amend the above-identified application as follows:

In the Claims:

Please cancel claims 1-80 without prejudice.

Please add new claims as follows:

81. (New) An ophthalmic composition comprising a liquid phase, said composition further comprising a component selected from the group consisting of magainin antimicrobial peptides, analogs of magainin antimicrobial peptides and mixtures thereof present in an amount effective as a preservative in said composition, wherein said composition includes a therapeutically effective component.

82. (New) The composition of claim 81 wherein said component is present in an amount less than about 10 milligrams per milliliter.

83. (New) The composition of claim 81 which further comprises water and an effective amount of a buffer component in an amount effective to provide said composition with a desired pH.

84. (New) The composition of claim 81 which further comprises an effective amount of a tonicity component in an amount effective to provide said composition with a desired osmolality.

85. (New) The composition of claim 81 wherein said liquid phase is selected from the group consisting of an oil-in-water emulsion, a solution and a suspension.

86. (New) The composition of claim 81 wherein said component is a magainin antimicrobial peptide.

D-2973

87. (New) The composition of claim 81 wherein said component is an analog of a magainin antimicrobial peptide comprising the amino acid sequence GIGKFLKKAKKFGKAFVKILKK.

88. (New) An ophthalmic composition comprising a liquid phase, said composition further comprising a component selected from the group consisting of magainin antimicrobial peptides, analogs of magainin antimicrobial peptides and mixtures thereof present in an amount effective as a preservative in said composition, wherein said component is a sole preservative in said composition.

89. (New) The composition of claim 88 wherein said component is present in an amount less than about 10 milligrams per milliliter.

90. (New) The composition of claim 88 which further comprises water and an effective amount of a buffer component in an amount effective to provide said composition with a desired pH.

91. (New) The composition of claim 88 which further comprises an effective amount of a tonicity component in an amount effective to provide said composition with a desired osmolality.

92. (New) The composition of claim 88 wherein said liquid phase is selected from the group consisting of an oil-in-water emulsion, a solution and a suspension.

93. (New) The composition of claim 88 wherein said component is a magainin antimicrobial peptide.

D-2973

94. (New) The composition of claim 88 wherein said component is an analog of a magainin antimicrobial peptide comprising the amino acid sequence GIGKFLKKAKKFGKAFVKILKK.

95. (New) An ophthalmic composition comprising a liquid phase, said composition further comprising a component selected from the group consisting of magainin antimicrobial peptides, analogs of magainin antimicrobial peptides and mixtures thereof present in an amount effective as a preservative in said composition, wherein said composition is an oil-in-water emulsion.

96. (New) The composition of claim 95 wherein said component is present in an amount less than about 10 milligrams per milliliter.

97. (New) The composition of claim 95 which further comprises an effective amount of a buffer component in an amount effective to provide said composition with a desired pH.

98. (New) The composition of claim 95 which further comprises an effective amount of a tonicity component in an amount effective to provide said composition with a desired osmolality.

99. (New) The composition of claim 95 wherein said component is a magainin antimicrobial peptide.

100. (New) The composition of claim 95 wherein said component is an analog of a magainin antimicrobial peptide comprising the amino acid sequence GIGKFLKKAKKFGKAFVKILKK.

101. (New) An ophthalmic composition comprising a liquid phase, said composition further comprising a component wherein said component is an analog of a magainin antimicrobial peptide comprising the amino acid sequence GIGKFLKKAKKFGKAFVKILKK, and wherein said component is present in an amount effective as a preservative in said composition.

102. (New) The composition of claim 101 wherein said component is present in an amount less than about 10 milligrams per milliliter.

103. (New) The composition of claim 101 which further comprises water and an effective amount of a buffer component in an amount effective to provide said composition with a desired pH.

104. (New) The composition of claim 101 which further comprises an effective amount of a tonicity component in an amount effective to provide said composition with a desired osmolality.

105. (New) The composition of claim 101 wherein said liquid phase is selected from the group consisting of an oil-in-water emulsion, a solution and a suspension.

106. (New) An ophthalmic composition comprising a liquid phase, said composition further comprising a component selected from the group consisting of magainin antimicrobial peptides, analogs of magainin antimicrobial peptides and mixtures thereof present in an amount effective as a preservative in said composition, wherein said composition is applied onto or into an eye.

D-2973

107. (New) The composition of claim 106 wherein said composition is a surgical irrigant.

108. (New) The composition of claim 106 wherein said component is present in an amount less than about 10 milligrams per milliliter.

109. (New) The composition of claim 106 which further comprises water and an effective amount of a buffer component in an amount effective to provide said composition with a desired pH.

110. (New) The composition of claim 106 which further comprises an effective amount of a tonicity component in an amount effective to provide said composition with a desired osmolality.

111. (New) The composition of claim 106 wherein said liquid phase is selected from the group consisting of an oil-in-water emulsion, a solution and a suspension.

112. (New) The composition of claim 106 wherein said component is a magainin antimicrobial peptide.

113. (New) An ophthalmic composition comprising a liquid phase, said composition further comprising an antimicrobial peptide mimetic present in an amount effective as a preservative in said composition.

114. (New) The composition of claim 113 wherein said component is present in an amount less than about 10 milligrams per milliliter.

115. (New) The composition of claim 113 which further comprises water and an effective amount of a buffer component in an amount effective to provide said composition with a desired pH.

116. (New) The composition of claim 113 which further comprises an effective amount of a tonicity component in an amount effective to provide said composition with a desired osmolality.

117. (New) The composition of claim 113 wherein said liquid phase is selected from the group consisting of an oil-in-water emulsion, a solution and a suspension.

118. (New) The composition of claim 113 wherein said composition includes a therapeutically effective component.

119. (New) A method of preserving an ophthalmic composition comprising:

contacting an ophthalmic composition with a magainin analog with an amino acid sequence comprising GIGKFLKKAKKFGKAFVKILKK in an amount effective as a preservative in said composition, wherein said composition is an oil-in-water emulsion.

120. (New) An ophthalmic composition comprising a magainin antimicrobial analog with an amino acid sequence comprising GIGKFLKKAKKFGKAFVKILKK present in an amount effective as a preservative in said composition, wherein said composition is provided in a multidose format and wherein said composition is an oil-in-water emulsion.

Remarks

As set forth above, applicant canceled claims 1-80 without prejudice. Applicant reserves the right to pursue the subject matter of those claims in the future at applicant's discretion. Claims 81-120 have been added and are currently pending.

The new claims have been added to more clearly define the present invention. Each of these new claims is fully supported by the present specification.

Applicant requests early and favorable action in the above-identified application. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Respectfully submitted,



Frank J. Uxa
Attorney for Applicant
Reg. No. 25,612
4 Venture, Suite 300
Irvine, CA 92618
Telephone: (949) 450-1750
Facsimile: (949) 450-1764